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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,098	04/21/2000	Elena Luriya	101.2	6742

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EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	18

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/557,098	Applicant(s) Luriya
	Examiner Gollamudi Kishore	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 16, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above, claim(s) *2-4 and 6-11* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 5, and 12-30* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The preliminary amendment and filing under 1.114 dated 1-16-03 are acknowledged.

Claims included in the prosecution are 1, 5 and 12-30.

Claim Rejections - 35 USC § 112

1. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

2. **Claims 1, 5 and 12-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations, "having no positively charged lipid but instead", and "having no phospholipid envelope or bioadhesive polymer coating" now introduced in claims 1 and 29 have no support in the specification as originally filed and therefore, deemed to be new matter.**

A careful review of the specification indicates that there is no support for the limitation that the lipid carrier should not be a positively charged lipid. The terms such as

'lipid carrier including' recited on page 4, line 3 of the specification, "lipids which have high adhesive capability to mucosal membranes include the various amphiphilic lipids such as phospholipids, for example" on page 12, lines 21-22 do not support the exclusion of positively charged lipids. Expressions such as "colloidal compositions which can include a micellar aggregate or mixed micelles dispersed in aqueous phase" (page 3, lines 9-11, page 6, lines 14-19 do not support the limitation "having no phospholipid envelop". Similarly, there is no support in the specification for the negative limitation that there should not be a polymer coating.

3. Claims 1, 5 and 12-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms, ratio (ration) and by (bys) in claims 1 and 29. The distinction between egg or soya lecithin and phosphatidylcholine in claims 1 and 29 is unclear. Phosphatidylcholine another name for lecithin. It is unclear as to what applicant intends to convey by 'gastrointestinal' in the independent claims. Does the expression mean that the composition is meant to be even oral entering the gastrointestinal mucosa as such so that the composition adheres to the gastrointestinal mucosa?

Aren't some of the compounds recited are trade names? Reciting the chemical names is suggested.

What is being conveyed in claim 22? The surfactants have the recited anionic functionality? Similar is the case with claim 23.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 12-21, 25, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakajima (5,338,761).

Nakajima discloses emulsion formulations containing egg or soya lecithin, a non-ionic surfactant, cholesterol and an active agent (antibiotic). The lipid : active agent amounts fall within the broad claimed range (note the abstract, col. 2, line 25 through col. 4, line 64).

6. Claims 1, 5, 12-18, 22, 26, 27 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Pittrof (5,376,646).

Pittrof discloses mixed micelle compositions for application to the mucosal membranes. The compositions contain soya lecithin, antibiotics or anti-inflammatory agents, an antioxidant, polyquaternium, glycocholic acid (anionic surfactant),

chlorhexidine salts, sweeteners. The lipid : active agent amounts fall within the broad claimed range (note the abstract, col. 1, line 48 through col. 3, line 6, Examples and claims).

> **(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.**

7. Claims 1, 5, and 12-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz (6,117,415).

Schwartz discloses oil in water emulsions containing either chlorhexidine or triclosan, egg lecithin, triglyceride, alpha-tocopherol hemisuccinate, Tween, peppermint oil. The composition also contains the other claimed surfactants. The particles sizes are 250 nm -350 nm (note the abstract, columns 2-3, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive, Applicant argues that in Schwartz there is a bioadhesive polymer coating. This argument is not found to be persuasive. According to Schwartz, the polymer performs two functions. At 0.5 % concentrations it has the mucoadhesive properties and at 1.5 % it has viscosity enhancing properties. Instant specification, on page 6 also recites a polymer such as polyethylene glycol which is a viscosity enhancing agent and applicant has not shown that this compound does not coat the micelles just as in the prior art.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 5, 12-18, 22, and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pittrof cited above.

The teachings of Pittrof have been discussed above. Pittrof does not teach entire claimed range of lipid to active agent. However, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to vary the active agent amounts from the guidance provided by Pittrof since the amounts of active agents to be administered depends on the condition of the disease and other factors. Pittrof also does not provide examples using chlorhexidine salts. However, from the guidance provided by Pittrof, it is deemed to be within the skill of the art to use these salts with the expectation of obtaining at least similar results. What is also lacking in Pittrof are the teachings of the sizes of the mixed micelles. In the absence of showing the criticality, sizes are deemed to be manipulatable parameters.

10. Claims 1, 5 and 12-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz (6,117,415) cited above.

The teachings of Schwarz have been discussed above. In essence, Schwarz teaches instant composition containing the same claimed components and the composition is meant as a mucoadhesive composition just as in instant invention. Schwarz in addition contains a polymer which is for enhancing the mucoadhesiveness of the composition. It would have

been obvious to one of ordinary skill in the art, in the absence of showing unexpected results, to exclude the polymer, if that enhanced mucoadhesiveness is not desired. Schwarz does not teach entire claimed range of lipid to active agent. However, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to vary the active agent amounts from the guidance provided by Schwarz, since as stated above, the amounts of active agents to be administered depends on the condition of the disease and other factors.

The examiner once again reminds applicants that the PTOL 1449 cannot be located in the file. Applicant is requested once again to provide a copy of the same.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

April 2, 2003